

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as Express Mail, Airbill No. EV 318 882 302 US, in an envelope addressed to: MS Patent Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

Dated: March 16, 2004

Signature: 

(Jasbir Sagoo, Ph.D.)

Docket No.: 102182-0039  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:

Matthew During et al.

Application No.: Not Yet Assigned <sup>2</sup> /

Confirmation No.:

Filed: Concurrently Herewith

Art Unit: 1632

For: GLUTAMIC ACID DECARBOXYLASE  
(GAD) BASED DELIVERY SYSTEMS

Examiner: A. M. Falk

**INFORMATION DISCLOSURE STATEMENT (IDS)**

MS Patent Application  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement accompanies the new patent application submitted herewith.

Copies of the references on the PTO/SB/08 are not provided.

Those patent(s) or publication(s) are not supplied because they were previously cited by or submitted to the Office in a prior application number 09/863,179, filed May 23, 2001 and relied upon in this application for an earlier filing date under 35 U.S.C. 120.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 141449, under Order No. 102182-0039.

Dated: March 16, 2004

Respectfully submitted,

By  \_\_\_\_\_

Jasbir Sagoo, Ph.D.

Registration No.: 51,177

NUTTER MCCLENNEN & FISH LLP

World Trade Center West

155 Seaport Boulevard

Boston, Massachusetts 02210-2604

(617) 439-2000

(617) 310-9000 (Fax)

Attorney for Applicant

1309579.1

Please type a plus sign (+) inside this box ☐

PTO/SB/08A (08-00)

Approved for use through 10/31/2002.OMB 0651-0031

U. S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO				<b>Complete If Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				Application Number	09/863,179-9640
				Filing Date	May 23, 2001
				First Named Inventor	Matthew J. During
				Group Art Unit	1645
				Examiner Name	Not Yet Assigned
Sheet	1	of	1	Attorney Docket Number	102182-0012

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
	AA	5,187,162		Marangos et al.	02-16-1993	
	AB	5,681,744		Greenstein	10-28-1997	

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	BA							

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	CA	Bu et al., "Two Human Glutamate Decarboxylases, 65-kDa GAD and 67-kDa GAD, Are Each Encoded by a Single Gene," <i>Proc. Natl. Acad. Sci. USA</i> , vol. 89, 2115-2119 (March 1992);	
	CB	Cao et al., "High-Titer, Wild-Type Free Recombinant Adeno-Associated Virus Vector Production Using Intron-Containing Helper Plasmids," <i>Journal of Virology</i> , vol. 74, no. 24, 11456-11463 (December 2000);	
	CC	Celada et al., "Gabaergic Control of Rat Substantia Nigra Dopaminergic Neurons: Role of Globus Pallidus and Substantia Nigra Pars Reticulata," <i>Neuroscience</i> , vol. 89, no. 3, 813-825 (1999);	
	CD	During et al., "Peroral Gene Therapy of Lactose Intolerance Using an Adeno-Associated Virus Vector," <i>Nature Medicine</i> , vol 4, no. 10 (October 1998);	
	CE	Kotin, Robert M., "Prospects for the Use of Adeno-Associated Virus as a Vector for Human Gene Therapy," <i>Human Gene Therapy</i> , vol. 5, 793-801 (1994);	
	CF	Linderfors, Nils, "Dopaminergic Regulation of Glutamic Acid Decarboxylase mRNA Expression and GABA Release in the Striatum: A Review," <i>Prog. Neuro-Psychopharmacol &amp; Biol. Psychiatry</i> , vol. 17, 887-903 (1993);	
	CG	Martin et al., "Are GAD <sub>65</sub> and GAD <sub>67</sub> Associated with Specific Pools of GABA in Brain?" <i>Perspectives on Developmental Neurobiology</i> , vol. 5, 119-129 (1998);	
	CH	Miller et al., "The Central Medial Nucleus: Thalamic Site of Seizure Regulation," <i>Brain Research</i> , vol. 508, 297-300 (1990);	
	CI	Schenk et al., "Immunization with Amyloid- $\beta$ Attenuates Alzheimer-Disease-Like Pathology in the PDAPP Mouse," <i>Nature</i> , vol. 400, 173-177 (July 1999);	
	CJ	Veliskova et al., "Subthalamic Nucleus: A New Anticonvulsant Site in the Brain," <i>Neuroreport</i> , vol. 7, no. 11, 1786-1788 (1996); and	
	CK	Xu et al., "Is the Anticonvulsant Effect of Substantia Nigra Infusion of Gama-Vinyl-GABA (GVG) Mediated by the GABA <sub>A</sub> Receptor in Rat Pups?" <i>Developmental Brain Research</i> , vol. 59, 17-21 (1991).	

Examiner Signature	Date Considered
--------------------	-----------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Unique citation designation number. <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>			<b>Complete If Known</b>		
			Application Number	09/863,179	
			Filing Date	May 23, 2001	
			First Named Inventor	Matthew J. During et al.	
			Group Art Unit	1642	
			Examiner Name	Not Yet Assigned	
Sheet	1	of	1	Attorney Docket Number	102182-12

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
	BA	WO 95/25805	9/28/95	PCT		

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume-issue number(s), publisher, city and/or country where published.	
	CL	Robert, JJ et al. "Adenovirus-Mediated Transfer of a Functional GAD Gene Into Nerve Cells: Potential For The Treatment of neurological Diseases" Gene Therapy, Vol. 4, No. 11, pgs. 1237-1245 (1997)	
	CM	Mi, Jie et al. "Recombinant Aden-Associated Virus (AAV) Drives Constitutive Production of Glutamate Decarboxylase In Neural Cell Lines" Journal of Neuroscience Research, Vol. 57, pgs. 137-148 (1999);	
	CN	New, Kent et al. "Novel Synthesis and Release of GABA In Cerebellar Granule Cell Cultures After Infection With Defective Herpes Simplex Virus Vectors Expressing Glutamic Acid Decarboxylase" Molecular Brain Research, Vol., pgs. 121-135 (1998);	
	CO	Navarro, V. et al. "Efficient Gene Transfer and Long-Term Expression In Neurons Using A Recombinant Adenovirus With A neuron-Specific Promoter" Gene Therapy, Vol. 6, pgs. 1884-1892 (1999)	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.